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苏州大学
卫生与环境技术研究所
最终报告

报告编号：SDWH-M201804494-3

参照 ISO 10993-10:2010 方法进行

有机硅精密薄膜

的皮内反应试验

0.9%氯化钠注射液浸提和芝麻油浸提

委托单位

杭州包尔得新材料科技有限公司

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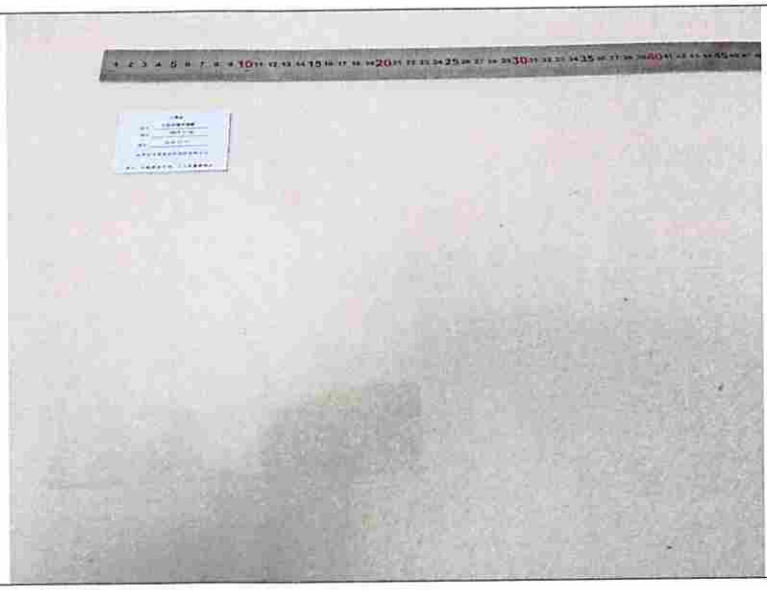
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试验确认与签名

试验样品	
接样日期：	2018-12-19
试验计划书编号：	SDWH-PROTOCOL-GLP-M201804494-3
试验计划书生效日期：	2018-12-25
试验操作开始日期：	2018-12-25
试验操作结束日期：	2019-01-05
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试验负责人

签发：　　2019-01-18 日期

授权签字人

苏州大学卫生与环境技术研究所

质量控制声明

试验过程恪守美国食品药品监督局《非临床研究实验室的良好实验室规范》21 CFR 58 部分。

豁免执行的条款为：21 CFR 条款 58.105 和 58.113，样品鉴定和样品与载体的混合物的稳定性。

质量办公室负责监督试验过程，监督日期见下表，并报告试验负责人和 SDWH 管理层。

监督	监督日期	数据报告试验负责人	数据报告 SDWH 管理层
试验过程	2019-01-02	2019-01-02	2019-01-18
原始数据	2019-01-18	2019-01-18	2019-01-18
报告	2019-01-18	2019-01-18	2019-01-18

质量办公室：周杰　　2019-1-18

QA　　日期

1.0 摘　要

试验样品有机硅精密薄膜浸提液与试验系统直接接触，观察其潜在的皮内刺激反应。

样品分别用 0.9%氯化钠注射液和芝麻油（SC 和 SO）浸提，将浸提液和空白对照液分别注射动物背部皮内，观察即时、(24±2)h、(48±2)h 和(72±2)h 后皮肤红斑和水肿等反应情况。

试验样品组极性和非极性浸提液皮内反应均未超过对照组，试验样品最终记分为 0。

在本次试验条件下，试验样品极性和非极性浸提液在兔皮肤未发现皮内刺激反应。

2.0 目　的

该试验系统用新西兰兔来检测皮内注射引起的皮内刺激反应，并类推到人类，但试验结果并不代表样品真正的皮内刺激反应危险性。

3.0 参考标准

医疗器械的生物学评价第 10 部分：刺激与皮肤致敏试验 ISO10993-10:2010

医疗器械的生物学评价第 12 部分：样品制备和参照样品 ISO10993-12:2012

医疗器械的生物学评价第 2 部分：动物保护要求 ISO10993-2:2006

4.0 执行规范

美国食品药品监督局《非临床研究实验室的良好实验室规范》21 CFR 58 部分

ISO/IEC 17025:2005《检测和校准实验室能力的通用要求》CNAS-CL01 检测和校准实验室能力认可准则（中国合格评定国家认可委员会 实验室认可证书 No. CNAS L2954）

检验检测机构资质认定评审准则 (中国国家认证认可监督管理委员会 资质认定 中国检验机构和实验室强制性批准 CMA 180015144061)

5.0 对照和试验样品确定

5.1 试验样品

名称：有机硅精密薄膜

来样原始状态：未灭菌

CAS 编号：未提供

型号：未提供

规格：未提供

批号：未提供

样品材料：聚有机硅氧烷

包装材质：未提供

性状：固体

颜色：无色透明

密度：1.0g/cm^3

稳定性：稳定

溶解度：不溶

保存条件：室温

预期临床用途：植入类产品-物理保护作用，不直接接触伤口

试验样品信息是由样品委托单位提供。委托单位负责遵守 GLP 试验有关样品的相关规定。

5.2 阴性对照

5.2.1 极性对照

名称：0.9%氯化钠注射液（SC）

制造商：辰欣药业股份有限公司

规格：500ml

批号：1810300722

性状：液体

颜色：无色

保存条件：室温

5.2.2 非极性对照

名称：芝麻油（SO）

制造商：吉安市绿源天然香料油提炼厂

规格：25kg

批号：20181207

性状：油状液体

颜色：淡黄色

保存条件：室温

5.3 阳性对照

5.3.1 极性对照

名称：20%十二烷基硫酸钠

制造商：Solarbio

规格：500g

批号：530M031

浓度：20%

溶剂：0.9%氯化钠注射液

配制日期：2018-12-25

性状：液体

颜色：无色透明

保存条件：室温

5.3.2 非极性对照

名称：20%十二烷基硫酸钠

制造商：Solarbio

规格：500g

批号：530M031

浓度：20%

溶剂：芝麻油

配制日期：2018-12-25

性状：悬浊液

颜色：黄色

保存条件：室温

6.0 试验系统鉴别

种属：新西兰白色纯种大白兔
数量：3 只
性别：雌性
重量：试验开始体重不低于 2.0kg
健康状况：健康未使用、初成年，未产且无孕
饲养：按组饲养在笼子内，做好标识编号、试验代号、试验开始日期。
动物鉴别：苦味酸染色
笼子：不锈钢笼子
适应期：在实验环境下 7 天。

7.0 饲养和护理

动物来源：苏州高新区镇湖实验动物科技有限公司 [许可证号：SCXK（苏）2015-0007]。
垫料：NA
饲料：实验兔全价颗粒饲料，苏州高新区镇湖实验动物科技有限公司
水：自来水（符合 GB 5749-2006 卫生标准）
室温：18-26℃
相对湿度：30%-70%
光照：每天需要 12 小时光照，全光谱日光灯
人员：检测人员有相应检测资质。
选择：选择健康未使用过的动物。
食物、水中无干扰试验数据污染物存在。

8.0 试验系统确认

依据现行试验标准，新西兰大白兔被指定作为评价原发性皮内刺激作用合适的动物模型。该试验采用 20%的十二烷基硫酸钠作为皮内刺激反应的阳性对照已经在苏州大学卫生与环境技术研究所试验得到证实。

9.0 给药途径确认

通过皮内注射将试验样品浸提液与试验系统接触，被认为是最佳接触方式。

10.0 试验设计

10.1 样品制备

样品制备见下表。

无菌操作取样		惰性容器内无菌震荡浸提			最终浸提液	
取样方式	实际取样	取样比例	SC	条件	pH	是否澄清
随机取样（撕去双面离型膜）	表面积 120cm^2	6cm^2: 1ml	20.0ml	50°C, 72h	6.0	澄清

无菌操作取样		惰性容器内无菌震荡浸提			最终浸提液	
取样方式	实际取样	取样比例	SO	条件	pH	是否澄清

随机取样（撕去双面离型膜）	表面积 120cm^2	6cm^2: 1ml	20.0ml	50°C, 72h	5.5	澄清

浸提前后浸提液状态未发生改变。浸提完成后 4℃保存，24h 内用于测试。浸提液 pH 值未经调整，未经过滤，离心，稀释等处理过程。不加供试品，同条件制备阴性对照液。

10.2 仪器设备

恒温振荡器（SDWH217）校正有效期（2019-05-15)
高压灭菌器（SDWH2097），校正有效期（2019-11-04）
电子秤（SDWH442），校正有效期（2019-05-15）
钢直尺（SDWH463），校正有效期（2019-08-22）

10.3 试剂

0.9%氯化钠注射液（SC）（辰欣药业股份有限公司，批号：1810300722 ）
芝麻油（SO）（吉安市绿源天然香料油提炼厂，批号：20181207）

10.4 试验步骤

试验前 4 -18 小时将动物背部脊柱两侧被毛除去，作为试验和观察部位。

在兔背一侧选 10 个点，每点间隔适当。5 个点注射 0.2ml 样品 SC 浸提液，5 个点注射 0.2ml 样品 SO 浸提液；兔背另一侧选 10 个点，每点间隔适当，5 个点注射 0.2ml SC 阴性对照液，5 个点注射 0.2ml SO 阴性对照液（见图 1）。

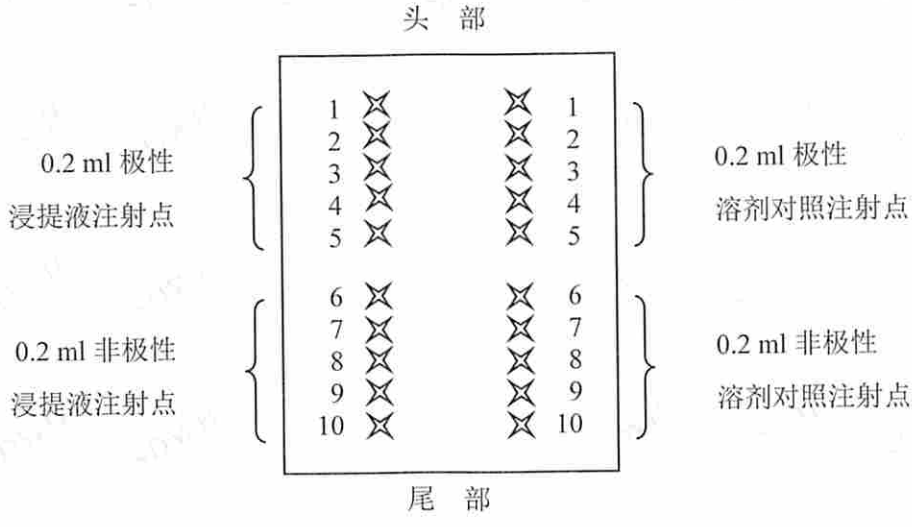


图1 注射点示意图

10.5 结果观察

观察即时、(24±2)h、(48±2)h 和(72±2)h 注射局部及周围皮肤组织反应，包括红斑、水肿和坏死等记录之。据红斑、水肿发生情况可记分为 0、1、2、3、4 标准记分等级。详见表 1。

表 1 皮内刺激反应记分标准

反应	记分	反应	记分
红斑		水肿	
无红斑现象	0	无水肿现象	0
轻度红斑(勉强可见)	1	轻度水肿(勉强可见皮肤增厚)	1
明显红斑(淡红色)	2	明显水肿(隆起而轮廓清楚)	2
中度红斑(鲜红色)	3	中度水肿(隆起近 1mm)	3
重度红斑(紫红色伴有轻微焦痂形成)	4	重度水肿(隆起大于 1mm)	4
刺激反应最高积分			8
注：其它副反应出现在皮肤刺激区域的应予记录和报告			

10.6 结果评价

仅使用(24±2) h, (48±2) h 和 (72±2) h 的观察数据进行计算。

将每只动物在每一规定时间的红斑和水肿刺激记分相加后再除以观察总数 15（3 个观察时间×5 个注射点），即为每只动物记分。

三只试验动物记分的平均数即为平均记分。

计算出对照平均记分，将试验样品平均记分减去该记分，即得出平均记分之差。该值即为试验样品的最终记分。

若试验样品最终记分不大于 1.0，则为符合试验要求。

10.7 结　果

实验过程中动物未出现异常症状或死亡。据观察，试验样品组极性和非极性浸提液皮内反应均未超过对照组， 最终记分均为 0。见表 2。

10.8 结　论

在本次试验条件下，试验样品的极性和非极性浸提液在兔皮肤未发现皮内刺激反应，符合试验要求。

11.0 记录存储

所有与本次试验有关的原始数据和记录都被保存在指定的 SDWH 档案文件中。

12.0 保密协议

签订检测委托合同即认为双方接受保密协议。

13.0 试验偏离声明

本次试验严格按照方案执行，未发生影响实验数据有效性的偏离。

表 2 皮内刺激反应结果观察

浸提液	动物编号	分组	反应	间隔时间(小时)/记分=5 点均值		
				24±2	48±2	72±2
SC	1	试验样品组	红斑	0	0	0
			水肿	0	0	0
		阴性对照组	红斑	0	0	0
			水肿	0	0	0
	2	试验样品组	红斑	0	0	0
			水肿	0	0	0
		阴性对照组	红斑	0	0	0
			水肿	0	0	0
	3	试验样品组	红斑	0	0	0
			水肿	0	0	0
		阴性对照组	红斑	0	0	0
			水肿	0	0	0
极性最终记分				0		
SO	1	试验样品组	红斑	0	0	0
			水肿	0	0	0
		阴性对照组	红斑	0	0	0
			水肿	0	0	0
	2	试验样品组	红斑	0	0	0
			水肿	0	0	0
		阴性对照组	红斑	0	0	0
			水肿	0	0	0
	3	试验样品组	红斑	0	0	0
			水肿	0	0	0
		阴性对照组	红斑	0	0	0
			水肿	0	0	0
非极性最终记分				0		

表 3 皮内刺激阳性对照

介质	动物编号	分组	反应	间隔时间(小时)/记分=5 点均值		
				24±2	48±2	72±2
SC	1	阳性对照	红斑	3.0	3.4	3.6
			水肿	3.4	2.4	1.6
		阴性对照组	红斑	0	0	0
			水肿	0	0	0
	2	阳性对照	红斑	3.2	3.4	3.8
			水肿	3.0	2.2	1.4
		阴性对照组	红斑	0	0	0
			水肿	0	0	0
	3	阳性对照	红斑	3.0	3.2	3.6
			水肿	2.6	2.2	1.4
		阴性对照组	红斑	0	0	0
			水肿	0	0	0
极性最终记分				5.6		
SO	1	阳性对照	红斑	3.0	3.6	3.8
			水肿	2.6	1.8	1.2
		阴性对照组	红斑	0	0	0
			水肿	0	0	0
	2	阳性对照	红斑	3.0	3.4	3.6
			水肿	3.2	2.2	1.4
		阴性对照组	红斑	0	0	0
			水肿	0	0	0
	3	阳性对照	红斑	3.0	3.6	3.8
			水肿	2.4	2.0	1.0
		阴性对照组	红斑	0	0	0
			水肿	0	0	0
非极性最终记分				5.4		

注：皮内刺激阳性对照每六个月进行一次，数据引用 SDWH-M201804440-3（完成日期：2018-12-28）。

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检测
TESTING
CNAS L2954

Sanitation & Environment technology Institute, Soochow University, Final Report

Report Number: SDWH-M201804494-3(E)

Intracutaneous Reactivity Test of
Precision silicone film
using ISO 10993-10:2010 Test Method
0.9% Sodium Chloride Injection Extract and Sesame Oil Extract

Sponsor
Hangzhou Bald Advanced Materials CO.,Ltd in English
No. 188, No. 5 Road, Xiasha Economic and Technological Development Zone, Jianggan District, Hangzhou, Zhejiang, China
Manufacturer
Hangzhou Bald Advanced Materials CO.,Ltd in English

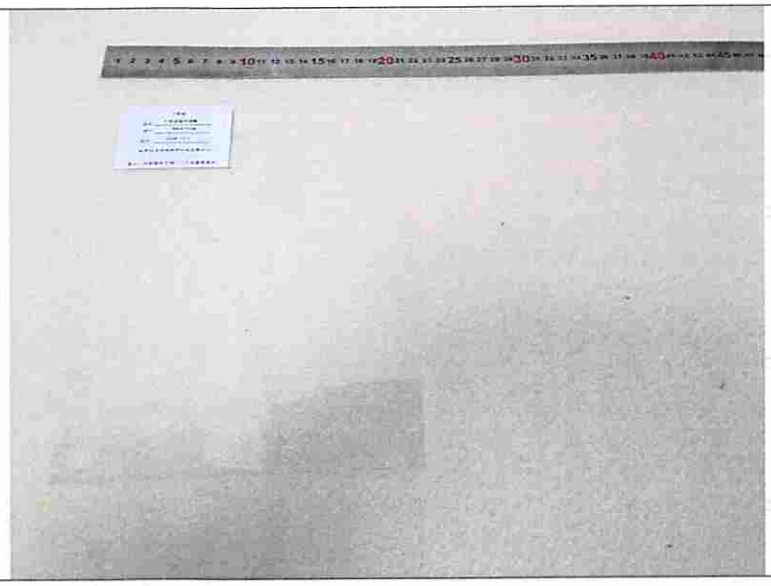
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SUPPLEMENTARY EXPLANATION

1. Please apply for rechecking within 15 days of receiving the report if there are any objections.
2. Any erasure or without special inspection and testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The result relate only to the articles tested.
5. The report shall not be reproduced except in full without the written approval of the institute.

STUDY VERIFICATION AND SIGNATURE

Test Article	
Test Article Receipt:	2018-12-19
Protocol No:	SDWH-PROTOCOL-GLP-M201804494-3
Protocol Effective Date:	2018-12-25
Technical Initiation Date:	2018-12-25
Technical Completion Date:	2019-01-05
Final Report Completion Date:	2019-01-18

Edited by : Feng Tancan 2019-01-18
Date

Checked by : Dai Mingwei 2019-01-18
Study Director Date

Approved by : Wang Chen 2019-01-18
Authorized signatory Date

苏州大学卫生与环境技术研究所 检验检测专用章 (2)

Sanitation & Environment Technology Institute, Soochow University

QUALITY ASSURANCE STATEMENT

This study was conducted in compliance with U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of SDWH, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Part 58.105 and 58.113.

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to SDWH's Management.

INSPECTIONS	DATE OF INSPECTION	DATE REPORTED STUDY DIRECTOR	DATE REPORTED MANAGEMENT
EXPERIMENTAL PROCEDURE	2019-01-02	2019-01-02	2019-01-18
RAW DATA	2019-01-18	2019-01-18	2019-01-18
FINAL REPORT	2019-01-18	2019-01-18	2019-01-18

Quality Assurance Unit: Zhan Ying 2019-01-18

QA Date

1.0 Summary

The extracts of the test article Precision silicone film (extraction in 0.9% sodium chloride injection and sesame oil) were evaluated for their potential to produce irritation after intracutaneous injection in New Zealand White rabbits. The test article sites did not show a significantly greater biological reaction than the sites injected with the solvent control. The final test article score was calculated to be 0.

The test results showed that the polar and non-polar test article extracts did not induce intratcutaneous reactivity in rabbit under the test condition.

2.0 Purpose

To evaluate the potential intracutaneous reactivity caused by intracutaneously inject the extract to rabbit and extrapolating the results to humans, but it does not establish the actual risk of irritation.

3.0 Reference

Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)

Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12:2012)

Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

4.0 Compliance

Good Laboratory Practice Regulations, 21 CFR, Part 58

ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories (CNAS-CL01 Accreditation Criteria for the competence of testing and calibration laboratories)

China National Accreditation Service for Conformity Assessment

Laboratory Accreditation Certificate No.CNAS L2954

Accreditation Criteria for the competence of Inspection Body (Certification and Accreditation Administration of the People's Republic of China CMA 180015144061)

5.0 Identification of test and control articles

5.1 Test article

Name: Precision silicone film
Test article initial state: Not Sterilized
CAS Code: Not supplied by sponsor (N/S)
Model: N/S
Size: N/S
Lot/ Batch: N/S
Test Article Material: Polyorganosiloxane
Packaging Material: N/S
Physical State: Solid
Color: Colorless and transparent
Density: 1.0g/cm^3
Stability: stable
Solubility: Insoluble
Storage Condition: Room Temperature
Intended Clinical Use: Implants - Physical protection, no direct contact with wounds

The information about the test article was supplied by the sponsor wherever applicable. The Sponsor was responsible for all test article characterization data as specified in the GLP regulations.

5.2 Negative Control
5.2.1 Polar Control
Name: 0.9% sodium chloride injection (SC)
Manufacturer: Chenxin Pharmaceutical Co., Ltd.
Size: 500ml
Lot/ Batch#: 1810300722
Physical State: Liquid
Color: Colourless
Storage Condition: Room Temperature
5.2.2 Non-polar Control
Name: sesame oil (SO)
Manufacturer: Ji'an luyuanxiangliao. Co. Ltd
Size: 25kg
Lot/ Batch#: 20181207
Physical State: Oily liquid
Color: Pale yellow
Storage Condition: Room Temperature
5.3 Positive Control
5.3.1 Polar Control
Name: 20% sodium dodecyl sulfate
Manufacturer: Solarbio
Size: 500g
Lot/ Batch#: 530M031
Concentration: 20%
Solvent: 0.9% sodium chloride injection (SC)
Date prepared: 2018-12-25
Physical State: Liquid
Color: Colorless Transparent
Storage Condition: Room Temperature
5.3.2 Non-polar Control
Name: 20% sodium dodecyl sulfate
Manufacturer: Solarbio
Size: 500g
Lot/ Batch#: 530M031
Concentration: 20%
Solvent: Sesame Oil
Date prepared: 2018-12-25
Physical State: Suspension
Color: Yellow
Storage Condition: Room Temperature

6.0 Identification of test system

Species: New Zealand white Rabbit (single strain).
Number: 3
Sex: Female
Weigh: Initial body weight not less than 2kg
Health status: Healthy, not previously used in other experimental procedures, young adult, nulliparous and not pregnant.
Housing: Animals were housed in cages identified by a card indicating the lab number, test code and

first treatment date.
Animal identification: Stain with picric acid
Cages: Stainless steel cage
Acclimation Period: 7 days under the same conditions as for the actual test

7.0 Animal Care and Maintenance

Animal purchase: Provided by Suzhou Experimental Animal Sci-tech Co., Ltd. <Permit Code: SCXK (SU) 2015-0007>
Bedding: NA
Feed: Rabbit Diet, Suzhou Experimental Animal Sci-tech Co., Ltd.
Water: Drinking water met the Standards for Drinking Water Quality GB 5749-2006
Animal room temperature: 18-26℃
Animal room relative humidity: 30%-70%
Lights: 12 hours light/dark cycle, full-spectrum lighting
Personnel: Associates involved were appropriately qualified and trained.
Selection: Only healthy, previously unused animals were selected.
There were no known contaminants present in the feed, water expected to interfere with the test data.

8.0 Justification of the test system

The rabbit is specified as an appropriate animal model for evaluating potential intracutaneous irritants by the current testing standards. Positive control 20% sodium dodecyl sulfate has been substantiated at SDWH with this method.

9.0 Route of administration

Intracutaneously inject the test article extract into the test system is optimal route of administration available in this test system.

10.0Experiment design

10.1Sample and Control Preparation

See the table below for test article extract preparation.

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container			Final Extract	
Sampling Manner	Actually sampling	Ratio	SC	Condition	pH	Clear or Not
Random Remove double sided release film	Surface area 120cm^2	6cm^2: 1ml	20.0ml	50°C, 72h	6.0	Clear

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container			Final Extract	
Sampling Manner	Actually sampling	Ratio	SO	Condition	pH	Clear or Not
Random Remove double sided release film	Surface area 120cm^2	6cm^2: 1ml	20.0ml	50°C, 72h	5.5	Clear

There was no change in the extraction solvent (pre- and post-extraction).
The extract was stored at 4℃ and tested within 24h after extraction without the process of pH value adjustment, filtering, centrifugation, dilution, etc.
The vehicle (without the test article) was similarly prepared to serve as the control.

10.2 Equipment

Constant Temperature Vibrator (SDWH217), Calibration Expire (2019-05-15)
Autoclave (SDWH2097), Calibration Expire (2019-11-04)
Electronic Scale (SDWH442), Calibration Expire (2019-05-15)
Steel Straight Scale (SDWH463), Calibration Expire (2019-08-22)

10.3 Reagents

0.9% sodium chloride injection (Chenxin Pharmaceutical Co., Ltd. Lot No: 1810300722)
Sesame oil (Ji'an luyuanxiangliao. Co. Ltd, Lot No: 20181207)

10.4 Experimental Procedure

Within a 4h to 18h period before testing, closely clip the fur on the back of the animals, allowing a sufficient distance on both sides of the spine for injection of the extracts.

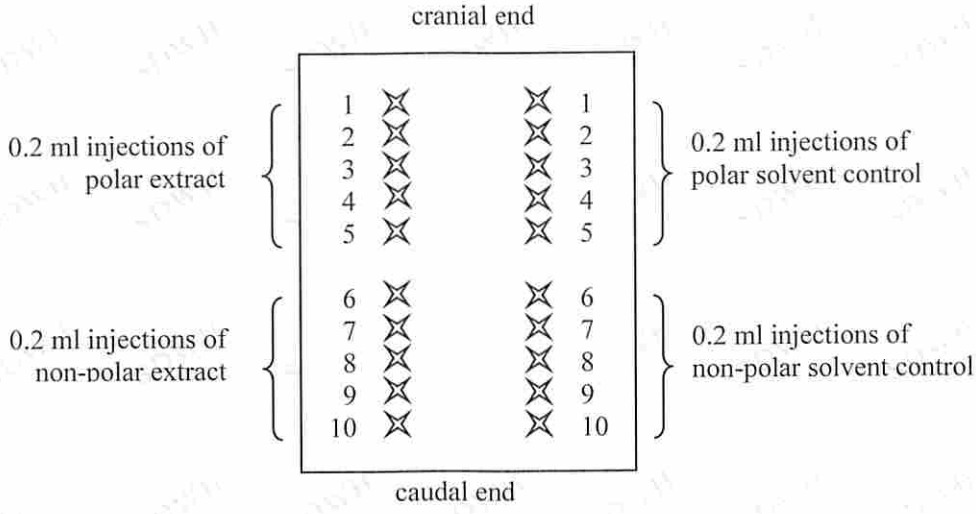


Figure 1 Arrangement of the injection site

Use the smallest needle appropriate to the viscosity of the test material for the intradermal injection. Inject intracutaneously 0.2ml of the extracts obtained with polar solvent at five sites and with non-polar solvent control at another five posterior sites on one side of each rabbit. Similarly, inject 0.2ml of polar solvent control at five sites and non-polar solvent control at another five posterior sites on the contralateral side of each rabbit (see Figure 1).

10.5 Observation of animal

Describe and score the skin reaction for erythema and oedema according to the scoring system given in Table 1 for each injection site at each time interval. Record the appearance of each injection site immediately after injection and at (24±2) h, (48±2) h and (72±2) h after injection.

10.6 Evaluation of results

Use only (24±2) h, (48±2) h and (72±2) h observations for calculation.
All erythema grades plus oedema grades (24±2) h, (48±2) h and (72±2) h were totalled separately for each test article or blank for each individual animal.
To calculate the score of a test article or blank on each individual animal, divide each of the totals by 15 (3 scoring time points×5 test or blank sample injection sites).
To determine the overall mean score for each test article and each corresponding blank, add the scores for the three animals and divide by three.
The final test article score can be obtained by subtracting the score of the blank from the test article score.
The requirements of the test are met if the final test article score is 1.0 or less.

Table 1 Grading system for intracutaneous (intrademal) reaction

Reaction	Numerical Grading
Erythema and Eschar Formation:	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet redness) to eschar formation preventing grading of	4
Oedema Formation:	
No edema	0
Very slight edema (barely perceptible)	1
Well-defined edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1mm)	3
Severe edema (raised more than 1mm and extending beyond exposure area)	4
Maximal possible score for irritation	8
Other adverse changes at the injection sites be recorded and reported	

10.7 Results

All animals were survived and no abnormal signs were observed during the study. According to what observed, the skin reaction of polar and non-polar extract on testing side did not exceed that on the control side. Thus, the final test article score was calculated to be 0. See table 2.

10.8 Conclusion

The test result showed that the polar and non-polar extract of the test article did not induce intracutaneous reactivity in rabbit. The test met the requirements of the standard under the test condition.

11.0 Record Storage

All raw data pertaining to this study and a copy of the final report are to be retained in designated SDWH archive.

12.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

13.0 Deviation statement

There were no deviations from the approved study protocol which were judged to have any impact on the validity of the data.

Table 2 Test Results of Dermal Observations

Extract	Rabbit No.	Group	Reaction	Interval (hours)/mean score		
				24±2 h	48±2h	72±2h
SC	1	Test Article	Erythema	0	0	0
			Oedema	0	0	0
		Negative Control	Erythema	0	0	0
			Oedema	0	0	0
	2	Test Article	Erythema	0	0	0
			Oedema	0	0	0
		Negative Control	Erythema	0	0	0
			Oedema	0	0	0
	3	Test Article	Erythema	0	0	0
			Oedema	0	0	0
		Negative Control	Erythema	0	0	0
			Oedema	0	0	0
Final score of polar extract				0		
SO	1	Test Article	Erythema	0	0	0
			Oedema	0	0	0
		Negative Control	Erythema	0	0	0
			Oedema	0	0	0
	2	Test Article	Erythema	0	0	0
			Oedema	0	0	0
		Negative Control	Erythema	0	0	0
			Oedema	0	0	0
	3	Test Article	Erythema	0	0	0
			Oedema	0	0	0
		Negative Control	Erythema	0	0	0
			Oedema	0	0	0
Final score of non-polar extract				0		

Table 3 Positive control

Extract	Rabbit No.	Group	Reaction	Interval (hours)/mean score		
				24±2 h	48±2h	72±2h
SC	1	Positive Control	Erythema	3.0	3.4	3.6
			Oedema	3.4	2.4	1.6
		Negative Control	Erythema	0	0	0
			Oedema	0	0	0
	2	Positive Control	Erythema	3.2	3.4	3.8
			Oedema	3.0	2.2	1.4
		Negative Control	Erythema	0	0	0
			Oedema	0	0	0
	3	Positive Control	Erythema	3.0	3.2	3.6
			Oedema	2.6	2.2	1.4
		Negative Control	Erythema	0	0	0
			Oedema	0	0	0
Final scores of polar positive control				5.6		
SO	1	Positive Control	Erythema	3.0	3.6	3.8
			Oedema	2.6	1.8	1.2
		Negative Control	Erythema	0	0	0
			Oedema	0	0	0
	2	Positive Control	Erythema	3.0	3.4	3.6
			Oedema	3.2	2.2	1.4
		Negative Control	Erythema	0	0	0
			Oedema	0	0	0
	3	Positive Control	Erythema	3.0	3.6	3.8
			Oedema	2.4	2.0	1.0
		Negative Control	Erythema	0	0	0
			Oedema	0	0	0
Final scores of non-polar positive control				5.4		

Note: Positive control performed once every six months, see SDWH-M201804440-3 (Completed Date: 2018-12-28).